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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,411	HON ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/06/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 22-35 are pending in the application.

Election/Restrictions

Due to the ambiguity regarding the election (the Examiner inadvertently omitted claims 22-35 from the restriction requirement) the previous requirement for restriction is hereby removed.

Claims 22-35 were examined on their merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,149,947. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-5 of '947 teach a method for treating a skin lesion comprising application of an active ingredient of inorganic solids comprising potassium ions, zinc ions calcium ions and rubidium ions along with a carrier such as cream or water.

Although the claims of '947 do not specifically state wherein the composition is applied over a period of multiple days, the ordinary artisan would have been motivated to repeatedly apply the composition until a positive, therapeutic effect was achieved.

Claims 22-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28 and 30-31 of copending Application No. 09/716,890. This is a provisional obviousness-type double patenting rejection. In the Instant case, Claims 28, 30 and 31 of '890 teach a method for enhancing wound healing comprising application of an active ingredient of inorganic solids comprising potassium ions, zinc ions calcium ions and rubidium ions along with a carrier such as cream or water. The claims of '890 do not specifically teach wherein the pH has a range of approximately 4-7, or wherein the pharmaceutically acceptable carrier is selected from ointments and creams for example

However, the specification of '890 which is the parent case to this Instant application, clearly teaches that the preferred pH of the compositions are 4-7 (p.4) and that carriers such as ointments and creams were suitable for use in the composition (p. 4).

Although the claims do not specifically state wherein the composition is applied over a period of multiple days, the ordinary artisan would have been motivated to repeatedly apply the composition until a positive, therapeutic effect was achieved.

Claims 22-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-41 of

copending Application No.10/676,754. This is a provisional obviousness-type double patenting rejection. In the Instant case, Claims 22-41 of '754 teach a method for enhancing wound healing comprising application of an active ingredient of inorganic solids comprising potassium ions, zinc ions calcium ions and rubidium ions along with a carrier such as cream or water, wherein the pH has a range of approximately 4-7, wherein the composition is applied over multiple days and wherein the composition of the method is substantially free of lead. Instant claims 22-36 are entirely within the scope of claims 22-41 of '754 and therefore Instant claims 22-35 are 'anticipated' by claims 22-41 of '754.

Claims 22-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-24 and 26-42 of copending Application No.10/645,412. This is a provisional obviousness-type double patenting rejection. In the Instant case, Claims 21-35 of '411 teach a method for treating melanoma comprising application of an active ingredient of inorganic solids comprising potassium ions, zinc ions calcium ions and rubidium ions along with a carrier such as cream or ointments for example, wherein the pH has a range of approximately 4-7. Instant claims 22-35 are entirely within the scope of claims 22-35 and therefore Instant claims 22-35 are 'anticipated' by claims 22-35 of '411. The claims of '411 do not specifically teach wherein the composition is applied multiple times.

Again, although the claims do not specifically state wherein the composition is applied over a period of multiple days, the ordinary artisan would have been motivated to repeatedly apply the composition until a positive, therapeutic effect was achieved.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating psoriasis or acne (what was already known in the art), does not reasonably provide enablement for treatment of all of the skin disorders as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to

practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

In the Instant case, Applicants are claiming numerous skin conditions which may be treated with a composition comprising rubidium and potassium ions, but have not provided any evidence of such in the Instant specification. It is noted that there is *not a single example in the Instant specification*, working or prophetic, which indicates that the product of the Instant claims; i.e., containing only rubidium and potassium for example disclosure would perform beneficially on any type of HVS originated skin disorders, cancerous ulcers, cancers, scars, psoriasis, wrinkles or any of the claimed disorders in claim 25. Although Applicants provide some examples in the Instant specification, these are not considered *'Working Examples'* because they do not correlate with the scope of the Instant claims which state that only potassium and rubidium can be used. On the contrary, the examples in the Instant specification are mainly drawn to wherein an 80% extract of oak bark was used as the active ingredient Since there are **no** working examples, then one must consider the guidance provided by the instant specification and the prior art of record.

Further, the instant specification provides absolutely no reasonable extrapolation to a known method for using minerals in treating acne and psoriasis with more aggressive skin disorders such as herpes simplex II caused by the HSV-II virus for example or cancerous ulcers. No mechanism of action has been established for the claimed composition and thus, a reasonable correlation cannot be achieved which would lead the skilled artisan to have any expectation that the composition would work for the claimed disorders.

The state of the art is unpredictable as it reflects that there is no cure for cancer and cancer treatments are rare. Bally et al. (US 5,595,756) stated, " Despite enormous investments of financial and human resources, no cure exists for a variety of diseases. For example, cancer remains one of the major causes of death. A number of bioactive agents have been found, to varying degrees, to be effective against tumor cells. However, the clinical use of such antitumor agents has been highly compromised because of treatment-limiting toxicities" Bally et al. (Col.1 lines 17-24). It is noted that the term 'prevention' is deemed to be a 'cure' because prevention of a disease state is broad enough to encompass complete inhibition; i.e., curing.

Therefore, in order to perform the methods as Instantly claimed would not just require a repetition of Applicant's work, but would entail a considerable amount of inventive contribution on the part of the skilled artisan involving undue experimentation. This experimentation would be undue considering that the skilled artisan would not have any reasonable expectation of success in carrying out the scope of the claimed invention due to lack of guidance in the specification with regard to the efficacy of the composition of the claims toward the claimed ailments as well as lack of teachings in the art with regard to the effectiveness of the claimed composition toward all of the claimed ailments.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as obvious over A in light of B in view of C, or alternatively, B in view of C.

Wherein; A= Carmel, A. (8/1991)

B= Genis et al. (US 6,458,338), and

C= Berger et al. (US 5,458,881).

Carmel, A. (8/1991) disclosed a composition sold by Orris Pharmaceuticals comprising dead sea minerals in products such as hand and foot creams, body lotion, shampoo and bath salts (see p. 5). The article also states that the minerals will treat psoriasis, acne or 'other skin conditions' (p. 5, last paragraph).

Dead sea minerals contain rubidium and potassium as evidenced by Genis et al. (US 6,458,388 B1)(see col.2, lines 63-67 and Table 1, col. 3).

Carmel did not specifically teach that the pH of their compositions was at a pH range of approximately 4-7 or between about 4.5 and about 7 or wherein the composition was applied to the skin over a period of multiple days or wherein the composition was substantially free of lead.

Berger et al. (US 5,458,881) taught that "it is often necessary to locate the pH of cosmetic compositions at approximately 5.5, namely at a pH approximately that of the skin, to decrease their aggressiveness to the skin" (Col.1, lines 47-50).

One of ordinary skill in the art would have been motivated to formulate either of the compositions disclosed by Carmel or Genis et al. to a pH in the range of approximately 4-7, specifically to a pH of approximately 5.5 in order to create a cosmetic which was delicate on the skin; i.e., 'pH balanced'. Therefore, it is well known in the cosmetic art that topical compositions are routinely formulated to the pH of skin. Rarely, except in the case of chemical peels, are cosmetics outside of this pH range. It is noted that neither reference stated that their cosmetic was intended for use as a chemical peel.

Further, one of ordinary skill in the art would have been motivated to repeatedly apply the composition until a positive, therapeutic effect was achieved.

This reference is cited merely to relay an inherent property and is not used as a basis for rejection *per se*.

Alternatively,

Genis et al. disclosed a cosmetic cream that contained dead sea salt that comprises rubidium and potassium ions (again, please see col.2, lines 63-67 and Table 1, col. 3).

Genis et al. did not specifically teach that their composition was at a pH range between about 4.5 and about 7 or between about 4.5 and about 5.5.

Berger et al. (US 5,458,881) taught that "it is often necessary to locate the pH of cosmetic compositions at approximately 5.5, namely at a pH approximately that of the skin, to decrease their aggressiveness to the skin" (Col.1, lines 47-50).

One of ordinary skill in the art would have been motivated to formulate either of the compositions disclosed by Carmel or Genis et al. to a pH in the range of approximately 4-7, specifically to a pH of approximately 5.5 in order to create a cosmetic which was delicate on the skin; i.e., 'pH balanced'. Therefore, it is well known

in the cosmetic art that topical compositions are routinely formulated to the pH of skin. Rarely, except in the case of chemical peels, are cosmetics outside of this pH range. It is noted that neither reference stated that their cosmetic was intended for use as a chemical peel.

Claims 22-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chase (1867) in view of Berger et al. (US 5,458,881).

Chase disclosed the use of an extract of oak bark ash for treating ulcerations of the skin (see p. 101). It is deemed that because the process for preparing the oak bark is substantially similar to the method for preparing the oak bark extract of the Instant claims, that the oak bark extract disclosed by Chase inherently included rubidium as well as zinc , potassium and calcium and was further substantially free of lead.

Chase did not specifically teach that the pH of the compositions was at a pH range of approximately 4-7 or between about 4.5 and about 7 or wherein the composition was present with a pharmaceutically acceptable carrier.

Berger et al. (US 5,458,881) taught that "it is often necessary to locate the pH of cosmetic compositions at approximately 5.5, namely at a pH approximately that of the skin, to decrease their aggressiveness to the skin" (Col.1, lines 47-50).

One of ordinary skill in the art would have been motivated to formulate the oak bark ash composition disclosed by Chase to a pH in the range of approximately 4-7, specifically to a pH of approximately 5.5 in order to create a topically administered medicament which was delicate on the skin; i.e., 'pH balanced'.

Carriers are well known in the pharmaceutical art to be admixed with therapeutically effective ingredients in order to 1) dilute therapeutics to varying dosages and 2) to ease administration of a therapeutic. One of ordinary skill in the art would have been motivated to add a carrier to the composition as disclosed by Chase in order to create a thicker composition which would adhere longer to the skin.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

12/05/05